THE CLAIMS

What is claimed is:

1. A buccal spray composition for transmucosal administration of testosterone or a pharmaceutically acceptable ester thereof comprising:

testosterone or a pharmaceutically acceptable ester thereof in an amount of between 0.1 and 25 percent by weight of the total composition;

a polar solvent in an amount between 10 and 97 percent by weight of the total composition; and

a propellant in an amount between 2 and 10 percent by weight of the total composition, wherein said propellant is a C_3 to C_8 hydrocarbon of linear or branched configuration.

2. The composition of claim 1, further comprising a taste mask and/or flavoring agent in an amount between 0.05 and 10 percent by weight of the total composition.

3. The composition of claim 2, wherein the polar solvent is present in an amount between 20 and 97 percent by weight of the total composition, the testosterone or a pharmaceutically acceptable ester thereof is present in an amount between 0.1 and 15 percent by weight of the total composition, the propellant is present in an amount between 2 and 5 percent by weight of the composition, and the taste mask and/or flavoring agent is present in an amount between 0.1 and 5 percent by weight of the total composition.

4. The composition of claim 3, wherein the polar solvent is present in an amount between 25 and 97 percent by weight of the total composition, the testosterone or a pharmaceutically acceptable ester thereof is present in an amount between 0.2 and 25 percent by weight of the total composition, the propellant is present in an amount between 2 and 4 percent by weight of the composition, and taste mask and/or flavoring agent is present in an amount between 0.1 and 2.5 percent by weight of the total composition.

5. The composition of claim 1, wherein the polar solvent is selected from the group consisting of polyethyleneglycols having a molecular weight between 400 and 1000, C_2 to C_8 mono- and poly-alcohols, and C_7 to C_{18} alcohols of linear or branched configuration.

6. The composition of claim 5, wherein the polar solvent comprises polyethylene glycol.

7. The composition of claim 5, wherein the polar solvent comprises ethanol.

8. The composition of claim 2, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

9. The composition of claim 1, wherein the propellant is selected from the group consisting of propane, *N*-butane, *iso*-butane, *N*-pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

10. The composition of claim 1, wherein the pharmaceutically acceptable ester of testosterone is selected from the group consisting of testosterone propionate, testosterone enanthate, and testosterone cypionate.

11. A method of administering testosterone or a pharmaceutically acceptable ester thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 1.

12. The method of claim 11, wherein the amount of the spray is predetermined.

13. A propellant free buccal spray composition for transmucosal administration of testosterone or a pharmaceutically acceptable ester thereof comprising:

testosterone or a pharmaceutically acceptable ester thereof in an amount between 0.005 and 55 percent by weight of the total composition; and

a non-polar solvent in an amount between 30 and 99 percent by weight of the total composition.

14. The composition of claim 13, further comprising a taste mask and/or flavoring agent in an amount between 0.1 and 10 percent by weight of the total composition.

15. The composition of claim 14, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

16. The composition of claim 13, wherein the solvent is selected from the group consisting of (C_2-C_{24}) fatty acid (C_2-C_6) esters, C_7-C_{18} hydrocarbons of linear or branched configuration, C_2-C_6 alkanoyl esters, and triglycerides of C_2-C_6 carboxylic acids.

17. The composition of claim 16, wherein the solvent is a triglyceride.

18. The composition of claim 13, wherein the pharmaceutically acceptable ester of testosterone is selected from the group consisting of testosterone propionate, testosterone enanthate, and testosterone cypionate.

19. A method of administering testosterone or a pharmaceutically acceptable ester thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 13.

20. The method of claim 19, wherein the amount of the spray is predetermined.

21. A propellant free buccal spray composition for transmucosal administration of testosterone or a pharmaceutically acceptable ester thereof comprising:

testosterone or a pharmaceutically acceptable ester thereof in an amount of between 0.001 and 60 percent by weight of the total composition; and

a mixture of a polar solvent and a non-polar solvent in an amount of between 30 and 99.69 percent by weight of the total composition, wherein the ratio of the polar solvent to the non-polar solvent ranges from 1:99 to 99:1.

22. The composition of claim 21, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

23. The composition of claim 22, wherein the polar solvent is present in an amount between 37 and 98 percent by weight of the total composition, the testosterone or a pharmaceutically acceptable ester thereof is present in an amount between 0.005 and 55 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.

24. The composition of claim 23, wherein the polar solvent is present in an amount between 60 and 97 percent by weight of the total composition, the testosterone or a pharmaceutically acceptable ester thereof is present in an amount between 0.01 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.

25. The composition of claim 21, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C_2 to C_8 mono- and poly-alcohols, and C_7 to C_{18} alcohols of linear or branched configuration and the non-polar solvent is selected from the group consisting of (C_2-C_{24})

fatty acid (C_2-C_6) esters, C_7-C_{18} hydrocarbons of linear or branched configuration, C_2-C_6 alkanoyl esters, and triglycerides of C_2-C_6 carboxylic acids.

26. The composition of claim 22, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

27. The composition of claim 21, wherein the pharmaceutically acceptable ester of testosterone is selected from the group consisting of testosterone propionate, testosterone enanthate, and testosterone cypionate.

28. A method of administering diazepam or a pharmaceutically acceptabl;e salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 21.

29. The method of claim 28, wherein the amount of the spray is predetermined.

30. A buccal spray composition for transmucosal administration of testosterone or a pharmaceutically acceptable ester thereof comprising:

testosterone or a pharmaceutically acceptable ester thereof in an amount between 0.05 and 50 percent by weight of the total composition;

a mixture of a polar and a non-polar solvent in an amount between 10 and 97 percent by weight of the total composition, wherein the ratio of the polar solvent to the non-polar solvent ranges from 1:99 to 99:1; and

a propellant in an amount between 5 and 80 percent by weight of the total composition, wherein said propellant is a C_3 to C_8 hydrocarbon of linear or branched configuration.

31. The composition of claim 30, further comprising a taste mask and/or flavoring agent is present in an amount between 0.01 and 10 percent by weight of the total composition.

32. The composition of claim 31, wherein the propellant is present in an amount between 10 and 70 percent by weight of the total composition, the solvent is present in an amount between 20 and 97 percent by weight of the total composition, the testosterone or a pharmaceutically acceptable ester thereof is present in an amount from between 0.1 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 1and 8 percent by weight of the total composition.

33. The composition of claim 30, wherein the propellant is selected from the group consisting of propane, *n*-butane, *iso*-butane, *n*-pentane, *iso*-pentane, *neo*-pentane, and mixtures thereof.

34. The composition of claim 33, wherein the propellant is *n*-butane or *iso*-butane and has a water content of not more than 0.2 percent and a concentration of oxidizing agents, reducing agents, Lewis acids, and Lewis bases of less than 0.1 percent.

35. The composition of claim 30, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C_2 to C_8 mono- and poly-alcohols, and C_7 to C_{18} alcohols of linear or branched configuration and the non-polar solvent is selected from the group consisting of (C_2-C_{24}) fatty acid (C_2-C_6) esters, C_7-C_{18} hydrocarbons of linear or branched configuration, C_2-C_6 alkanoyl esters, and triglycerides of C_2-C_6 carboxylic acids.

36. The composition of claim 30, wherein the pharmaceutically acceptable ester of testosterone is selected from the group consisting of testosterone propionate, testosterone enanthate, and testosterone cypionate.

37. A method of administering testosterone or a pharmaceutically acceptable ester thereof to a mammal, comprising spraying the oral mucosa of the mammal with the composition of claim 30.

38. The method of claim 37, wherein the amount of the spray is predetermined.

39. A method of treating hypogonadism in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 1.

40. A method of improving muscle development in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 1.

41. A method of stimulating erythropoiesis in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 1.

42. A method of treating anemia in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 1.

43. The method of claim 67, wherein the anemia is associated with failure of bone marrow, myelofibrosis, or renal failure.

44. A method of treating angioneurotic edema in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 1.

45. A method of treating growth retardation in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 1.

46. A method of treating carcinoma of the breast in a women by spraying the oral mucosa of the women with a therapeutically effective amount of the buccal spray of claim 1.

47. A method of treating osteoporosis in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 1.

48. A method of treating hypogonadism in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

49. A method of improving muscle development in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

50. A method of stimulating erythropoiesis in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

51. A method of treating anemia in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

52. The method of claim 51, wherein the anemia is associated with failure of bone marrow, myelofibrosis, or renal failure.

53. A method of treating angioneurotic edema in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

54. A method of treating growth retardation in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

55. A method of treating carcinoma of the breast in a women by spraying the oral mucosa of the women with a therapeutically effective amount of the buccal spray of claim 13.

56. A method of treating osteoporosis in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 13.

57. A method of treating hypogonadism in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

58. A method of improving muscle development in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

59. A method of stimulating erythropoiesis in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

60. A method of treating anemia in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

61. The method of claim 60, wherein the anemia is associated with failure of bone marrow, myelofibrosis, or renal failure.

62. A method of treating angioneurotic edema in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

63. A method of treating growth retardation in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

64. A method of treating carcinoma of the breast in a women by spraying the oral mucosa of the women with a therapeutically effective amount of the buccal spray of claim 21.

65. A method of treating osteoporosis in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 21.

66. A method of treating hypogonadism in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 30.

67. A method of improving muscle development in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 30.

68. A method of stimulating erythropoiesis in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 30.

69. A method of treating anemia in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 30.

70. The method of claim 69, wherein the anemia is associated with failure of bone marrow, myelofibrosis, or renal failure.

71. A method of treating angioneurotic edema in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 30.

72. A method of treating growth retardation in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 30.

73. A method of treating carcinoma of the breast in a women by spraying the oral mucosa of the women with a therapeutically effective amount of the buccal spray of claim 30.

74. A method of treating osteoporosis in a patient by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray of claim 30.